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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,765	08/24/2006	Greg P. Beer	47082-168USPX	2504

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EXAMINER	
SALZMAN, KOURTNEY R	
ART UNIT	**PAPER NUMBER**
1724	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,765	BEER ET AL.	
	Examiner	Art Unit	
	KOURTNEY R. SALZMAN	1724	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-11,21-32,37 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-11,21-32,37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/5/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2010 has been entered.

Summary

2. Claim 7 has been cancelled. Claims 1 and 21 have been amended. Claims 37 and 38 have been added.

3. Claims 1-6, 9-11, 21-32, 37 and 38 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 38 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Clam 38 is directed to "the method of claim 1", yet claim 1 is to a biosensor. Please fix the dependency of this claim to reflect the method claim 21 or the preamble to reflect the biosensor of claim 1.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims recite the limitations that only one enzyme is present, yet there is no support in the specification for this claim. The specification teaches the presence of "an enzyme", but in the interpretation of the examiner, this does not limit to only one enzyme necessarily as it doesn't preclude the use of more than one enzyme. From the specification, it does not seem that the number of enzymes present and the requirement of only one enzyme was contemplated prior to filing.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 21, 22, 25, 26 and 30-32are rejected under 35 U.S.C. 102(b) as being anticipated by GUO et al (US 6,033,866).

Regarding claim 1, GUO et al teaches a biosensor with a reagent layer 16 comprising an enzyme and second redox compound wherein the mediators or redox compounds can be found as mixtures (c. 6, l. 28-42). The mediator and internal reference are taught in column 6, lines 28-42 to be any number of combinations which inherently will nearly all have different redox potentials. Just the reagent layer is utilized to teach the presence of both mediators and both the mediator and internal reference are therefore present in a single layer. Since the claim does not require the mixture to be directly on top of either electrode, the claim is sufficiently fulfilled.

Regarding claim 2, in column 2, line 52 of GUO et al, ferrocyanide is identified as a possible internal reference species, known in the art to be a reduced form of a reversible redox couple. In combination with the ferrocyanide, numerous mediators can be utilized which have a lower redox potential, including that of the list of mediator components in column 6, l. 28-42.

Regarding claim 21, GUO et al teaches a biosensor with a reagent layer 16 comprising an enzyme and second redox compound wherein the mediators or redox compounds can be found as mixtures (c. 6, l. 28-42). The mediator and internal reference are taught in column 6, lines 28-42 to be any number of combinations which inherently will nearly all have different redox potentials. Just the reagent layer is utilized to teach the presence of both mediators and both the

mediator and internal reference are therefore present in a single layer. Since the claim does not require the mixture to be directly on top of either electrode, the claim is sufficiently fulfilled. The term batch is interpreted to mean that the pieces are brought together on the sensor wherein the batch is the necessary pieces of one sensor for example. Moreover, since each tangible piece is present discretely they are inherently added separately or in batch.

Regarding claims 22 and 30-32, in column 2, line 52 and column 6, lines 40-44 of GUO et al, ferrocyanide is identified as a possible internal reference species, known in the art to be a reduced form of a reversible redox couple. In combination with the ferrocyanide, numerous mediators can be utilized which have a lower redox potential from the list of possible mediators in column 6, lines 25-40. Moreover, ferricyanide is also identified in the opposite mediator mixture of GUO et al, as discussed in column 5, lines 13-20 as being a possible mediator. The substitution of any known mediator for another would be obvious as it would allow the same predictable functionality of electron transfer. This combination with the ferrocyanide would render equal redox potentials.

Regarding claims 25 and 26, these claims are directed to the method of operating the sensor while they depend of claim 21 which is directed to the method of making the sensor. Since the same materials (the numerous oxidizable species and mediators of use in GUO et al) and method of making are

present as the internal reference and mediator as required by claim 21, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself.

10. Claims 21-22, 30-32 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by HODGES et al (US PG PUB 2001/0052470).

Regarding claims 21, 30, 31 and 32, HODGES et al teaches a biosensor with reagent mixture comprising an enzyme (GOD), ferricyanide (mediator) and ferrocyanide (internal reference) in paragraph 9. The specification of the instant application discloses the internal reference can be a mediator species on page 3, line 24 of the instant application and this combination is taught on pages 15 and 16 of the specification as working in accordance with the present invention. Therefore, ferrocyanide can be interpreted to function as the internal reference. The chemical application or batch formation is discussed in paragraphs 69-70.

Regarding claim 22, the example of ferrocyanide as the internal reference and ferricyanide as the mediator is described on pages 15 and 16 of the specification to redox at the desired potentials.

Regarding claim 38, paragraph 70 of HODGES et al discloses the use of only one enzyme in the mixture.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 3-6, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUO et al (US 6,033,866), in view of BLOCZYNSKI et al (US 5,520,786).

GUO et al teaches all the limitations of claim 1, including the use of numerous mediators as the mediator of the instant application in column 6, lines 28-43 and column 5, lines 12-20.

Regarding claim 3, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (i.e. nickelocene or any of the other oxidized listed components of GUO et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 4, GUO et al teaches the ferrocyanide to be present as the internal reference.

Regarding claims 5 and 6, since the same materials are present as the internal reference and mediator, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself. For the purpose of this apparatus claim, the biosensor would be capable of reacting with the potentials as sufficiently required by the claim, as these are inherent reactions which the biosensor will perform when the process conditions specified are applied.

Regarding claim 23, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (i.e. any of the other oxidized listed components of GUO et al or any other identified electron transfer agent) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 24, GUO et al teaches the ferrocyanide to be present as the internal reference.

13. Claims 9-11, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUO et al (US 6,033,866), in view of NAGAKAWA et al (US PG PUB 2004/0245121 A1).

GUO et al teaches all the limitations of claim 1, including the use of numerous mediators as the mediator of the instant application in column 6, lines 28-43 and column 5, lines 12-20.

Regarding claims 9 and 27, NAGAKAWA et al teaches the use of a Ru complex mediator with substitutions, or ruthenium hexamine, as discussed in column 3, line 57- column 4, line 9.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (ruthenium hexamine, NAGAKAWA et al) for another known mediator (i.e. any of the other oxidized listed components of GUO et al or any other identified electron transfer agent) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 10 and 28, GUO et al teaches the ferrocyanide to be present as the internal reference.

Regarding claim 11, NAGAKAWA et al teaches the use of the mediator with glucose oxidase for glucose measurements in column 4, lines 19-29 as does GUO et al in column 2, l. 32-33.

14. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over HODGES (US PG PUB 2001/0052470), in view of BLOCZYNSKI et al (US 5,520,786).

HODGES et al teaches all the limitations of claim 21.

Regarding claim 23, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (ferricyanide, HODGES et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (Summary of invention and column 1, lines 47-50, BLOCZYNSKI et al)

Regarding claim 24, HODGES et al teaches the ferrocyanide to be present as the internal reference, as discussed in the above rejection.

Regarding claims 25 and 26, these claims are directed to the method of operating the sensor while they depend of claim 21 which is directed to the

method of making the sensor. Since the same materials and method of making are present as the internal reference and mediator as required by claim 21, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself.

15. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over HODGES et al (US PG PUB 2001/0052470), in view of NAGAKAWA et al (US PG PUB 2004/0245121 A1).

HODGES et al teaches all the limitations of claim 21.

Regarding claim 27, NAGAKAWA et al teaches the use of a Ru complex mediator with substitutions, or ruthenium hexamine, as discussed in column 3, line 57- column 4, line 9.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (ruthenium hexamine, NAGAKAWA et al) for another known mediator (ferricyanide, HODGES et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (NAKAGAWA et al, c. 1, l. 37-46)

Regarding claim 28, HODGES et al teaches the ferrocyanide to be present as the internal reference, as discussed the above rejection.

Regarding claim 29, HODGES et al teaches the enzyme to be GOD or glucose oxidase in paragraph 9. Furthermore, NAGAKAWA et al teaches the use of the mediator with glucose oxidase for glucose measurements in column 4, lines 19-29 but will also be effective with any oxidation-reduction enzyme, as in HODGES et al.

16. Claims 37 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over GUO et al (US 6,033,866).

Regarding claims 37 and 38, column 5, lines 61-63 teaches the use of only one enzyme system in the mixture. Moreover, example 4 teaches the system can be of use with one ferrocyanide (that of the second mediator layer which can include mixtures) and one enzyme. In the alternative, the use of a GOD system, in place of a HRP and GOX, would be both obvious as both function with the listed mediators for the same functionality of glucose reactivity.

Response to Arguments

17. Applicant's arguments filed November 5, 2010 have been fully considered but they are not persuasive.

b. Applicant argues on pages 6-7 that GUO et al fails to disclose the mixture to be on a single layer on at least one of the working electrode and the counter electrode prior to the introduction of the test sample.

i. Regarding the mixture being on a single layer, GUO et al teaches a mixture of mediators to be present in the one reagent layer 16, the second mediator layer, without the first mediator layer even being necessary.

Furthermore, the claim does not preclude more than one reagent layer to be in the sensor provided there is a layer which contains a mixture of at least two mediators which can be the mediator and internal reference of the instant application. Therefore, the current ground of rejection set forth by the examiner fulfills this aspect of the claim.

ii. Regarding the location of the mixture on each claim, when assembled the reagent layer will be chemically reachable and therefore "on" each electrode. The claim doesn't require direct contact and nothing to be present between the electrode and the reagent layer, therefore the limited interpretation by the applicant is not the broadest reasonable interpretation of "on".

iii. Finally, the addition of the mixture prior to introduction of the test sample is made clear in that the mixture of these mediators is present in a pre-manufactured reagent layer which is assembled, then used for sensing.

c. The applicant argues on page 7 that GUO et al has a two enzyme system and is therefore doesn't teach the invention.

iv. This is not part of independent claim 1, as this claim does not limit the use of multiple enzymes; it just requires that one be present. With the addition of this subject matter in claims 37 and 38, the new matter rejection under 35 USC 112 is submitted to the applicant. Moreover, the use of a GOD system, in place of a HRP and GOX, would be both

obvious, as both function with the listed mediators for the same functionality of glucose reactivity, and contemplated by GUO et al, as this is stated in the example 4.

d. The applicant argues on page 8 that HODGES et al fails to teach the formation of the reagent mixture then the placing of the mixture on the sensor prior to introduction of the sample.

v. The examiner disagrees. The formation of ferrocyanide, through oxidation, happens when exposed to air, prior to sensor assembly and clearly then prior to the testing or introduction of sample in paragraph 9. While the detection of the ferrocyanide happens following the introduction of sample, HODGES et al obviously argues that the ferrocyanide is present from oxidation with the air prior to the addition of sample.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6AM - 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAJ K OLSEN/
Primary Examiner, Art Unit 1724

krs

7/1/2011